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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,488	02/11/2004	Rafail Zubok	532/2x8 (F-280 Cont VII)	3255
27538	7590	10/22/2004		
KAPLAN & GILMAN, L.L.P. 900 ROUTE 9 NORTH WOODBIDGE, NJ 07095				
			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/776,488	Applicant(s) RAFAIL ZUBOK	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the anterior flange" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: The claim recites, "the apparatus includes a first member" and also recites, "the apparatus includes a second member". The applicant has used the phrase "includes", which is closed terminology. Therefore, if the apparatus *includes* a first member, the apparatus may only have a first member and not a second member. It is suggested to either change "includes" to --comprises-- or to change "the apparatus includes a second member" to recite --and a second member--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 14-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Khandkar et al. (US 2004/0133281 A1). See figures 16-21 and respective portions of the specification. Referring to claim 1, Khandkar discloses a method for replacing at least a portion of an intervertebral disc in a spinal column comprising removing the portion of the intervertebral disc from the spinal column and inserting an apparatus for replacing the portion of the intervertebral disc into an intervertebral disc space defined substantially between adjacent vertebral bones of the spinal column, and positioning the apparatus between the vertebral bones [0059], wherein the apparatus is operable to permit the adjacent vertebral bones to articulate relative to one another about at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space (fig.20, COR located below the space), and a second center of rotation for lateral bending that is located outside the intervertebral space (fig.21, COR located above the space).

Referring to claims 2, 4, and 5, Khandkar discloses the first and second centers of rotations to be located in opposite directions (above and below), one associated with flexion/extension (fig.20) and the other associated with lateral bending (fig.21).

Referring to claims 3 and 6, Khandkar discloses the apparatus to include a first member (60) having a vertebral contact surface (68) and an articulation surface (72), and a second member (62) having a vertebral contact surface (68) and an articulation surface (74), the members (60, 62) operable to articulate with respect to one another, where the articulation surfaces (72, 74) engage one another (fig.16-21).

Referring to claims 7-9, Khandkar discloses the first articulation surface (72) to have a concave arc (seen in fig.20), with radius A about an axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (seen in fig.21), with radius B about an axis substantially perpendicular to the lateral plane of the spinal column, and the second articulation surface (74) to have a convex arc (seen in fig.20), with radius C about an axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (seen in fig.21), with radius D about an axis substantially perpendicular to the lateral plane of the spinal column [0079].

Referring to claim 10, Khandkar discloses saddle shaped articulation surfaces (72, 74; see fig.16-21).

Referring to claim 14, Khandkar discloses the vertebral contact surfaces (68) to be curvate (see fig.16-21; convex or domed surfaces [0077]).

Referring to claim 15, Khandkar discloses at least one spike (66; [0077]) on the vertebral contact surfaces (68), and urging the spikes (66) into the vertebral bones.

Referring to claims 16-19, Khandkar discloses the apparatus to permit the vertebral bones to axially rotate through a limited range of angles, *about* plus/minus three degrees [0079, 0080].

Claims 1-10 and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree et al. (US 2004/0024462 A1). Referring to claim 1, Ferree discloses a method for replacing at least a portion of an intervertebral disc in a spinal column comprising removing the portion of the intervertebral disc from the spinal column and inserting an apparatus for replacing the portion of the intervertebral disc into an intervertebral disc space defined substantially between adjacent

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vertebral bones of the spinal column [0002], and positioning the apparatus between the vertebral bones, wherein the apparatus is operable to permit the adjacent vertebral bones to articulate relative to one another about at least one of a first center of rotation for at least one of flexion and extension (COR below space, see fig.3B) that is located outside the intervertebral disc space, and a second center of rotation for lateral bending (COR above space, see fig.3A) that is located outside the intervertebral space.

Referring to claims 2, 4, and 5, Ferree discloses the first and second centers of rotations to be located in opposite directions (above and below), one associated with flexion/extension (fig.3B, COR below space) and the other associated with lateral bending (fig.3A, COR above space).

Referring to claims 3 and 6, Ferree discloses the apparatus to include a first member (top member, fig.3A, 3B) having a vertebral contact surface (top surface) and an articulation surface (bottom surface), and a second member (bottom member in fig.3A, 3B) having a vertebral contact surface (bottom surface) and an articulation surface (top surface), the members operable to articulate with respect to one another, where the articulation surfaces engage one another (see figs).

Referring to claims 7-9, Ferree discloses the first articulation surface (bottom surface of top member in figs) to have a concave arc (fig.3B), with radius A about an axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (fig.3A), with radius B about an axis substantially perpendicular to the lateral plane of the spinal column, and the second articulation surface (top surface of bottom member in figs) to have a convex arc (fig.3B), with radius C about an axis substantially perpendicular to the anterior-posterior plane of

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the spinal column, and a concave arc (fig.3A), with radius D about an axis substantially perpendicular to the lateral plane of the spinal column.

Referring to claim 10, Ferree discloses saddle shaped articulation surfaces [0007].

Referring to claim 15, Ferree discloses at least one spike on the vertebral contact surfaces, and urging the spikes into the vertebral bones [projections, 0009].

Referring to claims 16-19, Ferree discloses the apparatus to permit the vertebral bones to axially rotate through a limited range of angles, *about* plus/minus three degrees [limit rotation, therefore, minimal rotation will occur, 0007].

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khandkar et al. (US 2004/0133281 A1) in view of Gordon (US 6,228,118 B1). Khandkar discloses a method of replacing a portion of an intervertebral disc substantially as claimed (see above). Khandkar discloses replacing the portion with an apparatus including two members (60, 62), which articulate with respect to one another (fig.20, 21), however do not disclose the members (60, 62) to have flanges with through holes. Gordon teaches in the same field of intervertebral discs, a method of replacing a portion of a disc with an apparatus having two members (10, 12), the members having flanges (16) with two through holes (22) for screws (14), in order to better

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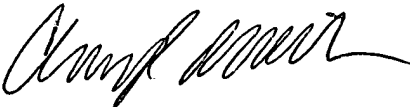
secure the members to the vertebral bones (col.2, lines 15-38; col.3, lines 9-16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Khandkar's method of replacing a disc with an apparatus, with Gordon's teaching of having flanges with holes on the apparatus member, in order to replace the disc with an apparatus having a more secure attachment.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Cheryl Miller

  
BRUCE SNOW  
PRIMARY EXAMINER